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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,292

Applicant(s)

BERTHOLD, ACHIM

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 26 August 2002 (paper no. 13).

2a) ☒ This action is **FINAL**.

2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-15 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.

4) ☐ Interview Summary (PTO-413) Paper No(s). _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the IDS filed 08/13/02 and the
~~Amendment filed 08/26/02.~~

The 35 USC 112, first paragraph rejections have been withdrawn.

Claims 1-15 are pending. Claims 1-15 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for
all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable
over Kwiatek *et al.* (US Pat. No. 5,503,844, collectively, "Kwiatek") in view of
Becher (US Pat. No. 5,066,494).

Kwiatek *et al.* teach a transdermal therapeutic patch for the controlled
release of lovastatin to the skin or mucous membranes (see reference column 1,
lines 54-67); (column 2, lines 1-40); (column 8, lines 12-65); (column 16, lines 58-
67); (column 17, lines 1-14); (column 24, lines 23-58).

Kwiatek while teaching a transdermal patch for the release of lovastatin to the skin or mucous membranes, do not explicitly teach a patch in which the active substance is contained within a self-adhesive matrix layer, but rather in a foam, which requires a laminate to be affixed on to the skin or mucosa for the release of the active agent.

Becher teaches a transdermal therapeutic patch comprising a contact adhesive layer as a means of fixing the therapeutic system on to human skin (see reference column 2, lines 32-56) and (column 4, lines 1-27). Therefore, it would have been obvious to one of ordinary skill in the pharmaceutical art at the time the invention was made to use a therapeutic patch delivery system consisting of an adhesive layer as a means for affixing the therapeutic composition on to the skin of a patient. The expected result would be a transdermal patch, which adheres well to the skin and offers effective administration of the active substance.

Response to Arguments

Applicant's arguments filed 08/26/02 have been fully considered but they are not persuasive. The applicant argued regarding the transdermal patch of Kwiatek ('844), "due to this construction, the active agent present in the foam

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layer cannot permeate from the second surface wherein the inner surface is affixed to the second surface of the foam layer." The applicant also argued, "an additional drawback is that a foam such as the one described in Kwiatek et al. "844 is unable to control the flux of the active substance from the patch onto and through the skin of the patient."

This argument has been carefully considered, but is not found to be persuasive. The present invention is drawn to a preparation containing at least one active substance having an influence on the blood lipid levels of an organism, wherein the preparation is present in the form of a transdermal therapeutic patch containing the active substance in a self adhesive polymer matrix layer, an impermeable backing layer and wherein the release of the active substance is essentially constant over a 72-hour period. Kwiatek teaches a transdermal patch for the controlled release of lovastatin to the skin or mucous membranes wherein the active substance is contained in foam. Kwiatek, while not teaching a self-adhesive polymer matrix, does teach a transdermal patch having an active agent permeable adhesive layer and teaches the generic concept of the active agent being contained within the adhesive itself (see col. 11, lines 28-67); (col. 12, lines 1-51). Kwiatek teaches an active agent flux enhancer wherein the active ingredients can migrate to the other layers (col. 12, lines 37-51). The prior art recognizes the same ingredients in a similarly formulated transdermal form and therefore the properties resulting would also tend to be the same as the applicant's invention. Furthermore it is not necessary that the prior art recognize each and every property discovered by the applicant,

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merely that there be present the teaching of a transdermal preparation containing an active substance contained within an adhesive layer and wherein the active substance is one having an influence on blood lipid levels.

The applicant argued regarding the secondary reference of Becher, "that ~~Becher '494 does not provide any additional information to the teaching of~~ Kwiatek et al. '844 which would facilitate a person skilled in the art to creating the present invention since both references suggest how to affix an otherwise non-adhesive system to a patient's skin by using an additional adhesive means." This argument has been fully considered but is not found to be persuasive. The teachings of Kwiatek have been discussed above. Kwiatek does not teach a self-adhesive matrix layer as instantly claimed, but rather teaches a foam containing the active substance and also teaches an active agent permeable adhesive layer wherein the active substance is contained within the adhesive. Becher teaches a similar transdermal therapeutic patch comprising a contact adhesive layer as a means of fixing the therapeutic system onto the skin (col. 2, lines 32-56); (col. 4, lines 1-27). Both references relied upon teach the use of an adhesive layer containing an active substance contained within. There is no distinction observed between the instant claims and the prior art, since the prior art teaches a similar transdermal preparation with the same claimed ingredients for the same intended purpose.

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The applicant argued regarding the specific adhesive qualities of the self-adhesive matrix layer in that "the self-adhesive quality of the matrix layer is a significant departure from the referenced prior art which specifically employs the use of an additional adhesive means to affix the TTS to the patient's skin."

This argument has been thoroughly considered, but is not found to be persuasive. ~~The prior art teaches an active agent permeable adhesive layer~~ wherein the active substance is contained within the adhesive itself and both Kwiatek and Becher teach a transdermal patch for delivery of an active agent to the skin. Regarding the specific adhesive qualities of the self-adhesive matrix layer of the present invention, the instant generic claim has been amended to show that the release of the active substance is essentially constant over a period of at least 72 hours. However, the applicant has not shown that the transdermal formulation of the prior art is not capable of providing sufficient adhesive qualities, such as a constant release rate over a 72-hour period, and achieving the same results therewith. The prior art teaches the generic concept of controlled release of an active agent to the skin or mucosa in a similar formulation with the same ingredients and therefore the release rates or release properties would also to be the same.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
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